

§ 870.4330

filed with the Food and Drug Administration on or before September 21, 2004, for any cardiopulmonary bypass pulsatile flow generator that was in commercial distribution before May 28, 1976, or that has, on or before September 21, 2004, been found to be substantially equivalent to any cardiopulmonary bypass pulsatile flow generator that was in commercial distribution before May 28, 1976. Any other cardiopulmonary bypass pulsatile flow generator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 69 FR 34920, June 23, 2004]

§ 870.4330 Cardiopulmonary bypass on-line blood gas monitor.

(a) *Identification.* A cardiopulmonary bypass on-line blood gas monitor is a device used in conjunction with a blood gas sensor to measure the level of gases in the blood.

(b) *Classification.* Class II (performance standards).

§ 870.4340 Cardiopulmonary bypass level sensing monitor and/or control.

(a) *Identification.* A cardiopulmonary bypass level sensing monitor and/or control is a device used to monitor and/or control the level of blood in the blood reservoir and to sound an alarm when the level falls below a predetermined value.

(b) *Classification.* Class II (performance standards).

§ 870.4350 Cardiopulmonary bypass oxygenator.

(a) *Identification.* A cardiopulmonary bypass oxygenator is a device used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Guidance for

21 CFR Ch. I (4-1-05 Edition)

Cardiopulmonary Bypass Oxygenators 510(k) Submissions."

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

§ 870.4360 Nonroller-type cardiopulmonary bypass blood pump.

(a) *Identification.* A nonroller-type cardiopulmonary bypass blood pump is a device that uses a method other than revolving rollers to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987]

§ 870.4370 Roller-type cardiopulmonary bypass blood pump.

(a) *Identification.* A roller-type cardiopulmonary bypass blood pump is a device that uses a revolving roller mechanism to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

(b) *Classification.* Class II (performance standards).

§ 870.4380 Cardiopulmonary bypass pump speed control.

(a) *Identification.* A cardiopulmonary bypass pump speed control is a device used that incorporates an electrical system or a mechanical system, or both, and is used to control the speed of blood pumps used in cardiopulmonary bypass surgery.

(b) *Classification.* Class II (performance standards).

§ 870.4390 Cardiopulmonary bypass pump tubing.

(a) *Identification.* A cardiopulmonary bypass pump tubing is polymeric tubing which is used in the blood pump head and which is cyclically compressed by the pump to cause the blood to flow through the cardiopulmonary bypass circuit.

(b) *Classification.* Class II (performance standards).